UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,225	06/30/2003	David Hung	005284.00198	1750

38732 7590 05/02/2006

CYTYC CORPORATION
250 CAMPUS DRIVE
MARLBOROUGH, MA 01752

EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,225	HUNG ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,32-39 and 45-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18, 32-39 and 45-70* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Hung et al.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim 8, drawn to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, wherein examining the ductal fluid comprises cytological examination of ductal epithelial cells in the sample, classified in class 435, subclass 7.23.

   II. Claims 9, drawn to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, wherein examining the ductal fluid comprises detection of an estrogen receptor in the ductal epithelial cells, classified in class 435, subclass 7.2.

   III. Claim 10, drawn to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, wherein examining the ductal fluid comprises detecting the absence of TGF-beta in the ductal fluid, classified in class 435, subclass 7.1.

IV. Claim 11, drawn to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, wherein examining the ductal fluid comprises detection of a change in a level of a marker, classified in class 435, subclass 7.1.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single marker from Claim 11 (i.e. carcinoma embryonic antigen (CEA), prostate specific antigen (PSA), erbB2 antigen, gross cystic disease fluid protein-15 (GCDFP-15), and lactose dehydrogenase). This election should not be construed as an election of species. This is a restriction requirement. Each of the markers is structurally and functionally distinct molecule that would require separate search.

V. Claim 12, drawn to a method for identifying asymptomatic patients who have a likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, wherein examining the ductal fluid comprises detecting a chromosomal abnormality in the ductal epithelial cells, classified in class 4.35, subclass 6.

VI. Claims 32-39, drawn in part to a method for identifying patients who have a decreased likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast

cancer, comprising determining the absence of estrogen receptor, classified in class 4.35, subclass 7.2.

VII. Claims 32-39, drawn in part to a method for identifying patients who have a decreased likelihood of benefiting from the administration of an estrogen activity modulator for risk reduction or therapeutic treatment of breast cancer, comprising determining the presence of TGF beta, classified in class 4.35, subclass 7.1.

VIII. Claims 45-59 and 69-70, drawn to a method of monitoring on-going therapy in a patient at risk of or suffering from breast cancer, classified in class 4.35, subclass 4.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single marker from Claim 53 (i.e. neoplastic ductal epithelial cells, transforming growth factor-β (TGF-β), estrogen receptor, chromosomal abnormality, carcinoma embryonic antigen (CEA), prostate specific antigen (PSA), erbB2 antigen, gross cystic disease fluid protein-15 (GCDFP-15), and lactose dehydrogenase). This election should not be construed as an election of species. This is a restriction requirement. Each of the markers is structurally and functionally distinct molecule that would require separate search.

IX. Claims 60-68, drawn to a method for analyzing ductal fluid, classified in class 4.35, subclass 4.

If applicants elect this group for prosecution on the merits, applicants are further required to select a single marker from Claim 60 (i.e. transforming growth factor-β (TGF-β), estrogen receptor, chromosomal abnormality), and a single second marker from claim 62 (i.e. carcinoma embryonic antigen (CEA), prostate specific antigen (PSA), erbB2 antigen, gross cystic disease fluid protein-15 (GCDFP-15), and lactose dehydrogenase, epidermal growth factor receptor (EGFR), and p53). This election should not be construed as an election of species. This is a restriction requirement. Each of the markers is structurally and functionally distinct molecule that would require separate search.

2. Claims 1-7 and 13-18 are linking claims which link groups I-V together. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP j 804.01.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that these methods would be used together. The method for identifying asymptomatic patients (groups I-V), the method for identifying patients who have a decreased likelihood of benefiting from the administration of an estrogen activity modulator (groups VI-VII), the method of monitoring on-going therapy in a patient at risk of or suffering from breast cancer (group VIII, and the method for analyzing ductal fluid (group IX) are all unrelated as they have different functions and different effects. Each method comprises distinct steps and utilizes different products which demonstrates that each method has a different mode of operation. Groups I-V are for identifying asymptomatic patients who have likelihood of benefiting from the administration of an estrogen activity modulator, wherein the patients have no symptoms of breast cancer, or are negative in a standard cancer test or show inconclusive or ambiguous results from a standard cancer test (see claim 14); groups VI-VII are for identifying patients who have a decreased likelihood of benefiting from the administration of an estrogen activity modulator, wherein patients are receiving an ongoing therapy for risk reduction or treatment of breast cancer, or patients has been found to have precancer or cancer of breast (see claims 35 and 37); group VIII is for monitoring on-going therapy in a patients at risk of or suffering from breast cancer,

comprising measuring the level of a marker at different time points; group IX is for analyzing ductal fluid, wherein the step of identifying of patients for likelihood or decreased likelihood of benefiting from the administration of an estrogen activity modulator is not required. Therefore, each group has different functions. Groups I-V further differ from each other in that the method used to examine the ductal fluid is distinct in each of the groups. For group I, the ductal epithelial cells are examined cytologically; for group II, an estrogen receptor in the ductal epithelial cells is detected; for group III, the TGF-beta is detected; for group IV, a marker such as CEA or PSA is detected; for group V, the presence of a chromosomal abnormality is detected. Therefore, groups I-V are distinct. Groups VI and VII further differ from each other in that the different marker is detected. For group VI, the estrogen receptor is detected; for group VII, the TGFbeta is detected in group VII. For these reasons the Inventions VI-VII are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. Searching groups I-XI are not coextensive. As such, it would be burdensome to search the inventions of Groups I-IV together.

4. This application contains claims directed to the following patentably distinct species: a selective estrogen receptor modulator (SERM), an estrogen antagonist, a modulator of estrogen synthesis, tamoxifen, raloxifene, EM800, droloxifene, iosdroxifene, RU39411, RU58668, ICI 164384, faslodex, soy, a soy isoflavone, a gonadotropin releasing hormone agonist, and an aromatase inhibitor. The species are

independent or distinct because each of the estrogen activity modulators is a structurally and functionally distinct molecule, which would require separate search.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-14, 47, and 52 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hong Sang
Art Unit 1643
Apr. 25, 2006

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER